REMARKS

Claims 1-8, 11, 20-22, 27, 34, and 36 are pending. Claims 9-10, 12-19, 23-26, 28-33, 35, and 37-40 are cancelled.

Claim 1 is currently amended to specify that the IRM compound activates TLR 6, 7, and/or 8 and that the IRM compound is selected from certain small molecule compound classes. Support can be found, e.g., at page 10, lines 27-29 and original claims 14 and 17.

§ 112, 1st paragraph rejection

Claims 1-8, 11, 14, 17, 20-22, 27, 34, and 36 were rejected under 35 USC § 112, first paragraph, as allegedly lacking enablement. In particular the Office Action asserts that the specification does not reasonably enable delivering each and every IRM to various mucosal surfaces so as to achieve imunomodulation with reduced irritation of the mucosal surface from the IRM compound by applying the IRM compound in repeated application to the mucosal surface and removing at least 50% of the IRM compound after each application. In addition, claims 27, 34, and 36 also allegedly lack enablement for general treatment of conditions associated with any mucosal surface with an IRM compound.

Applicants respectfully traverse because it is believed that the claims, particularly as amended, are fully enabled and that it would not require undue experimentation for one skilled in the art to practice the claimed invention. The claimed compounds are small molecules that work through a common mechanism of action in the immune system (activating through TLRs 6, 7, and/or 8).

As discussed in previous submissions, the present invention is based in part on the discovery that IRM compounds activate or "kick-start" immune response for an extended period after the IRM is no longer present. This is a very useful and generally applicable discovery because it allows one to reduce unwanted side effects by removing the IRM compound from contact before the side effects would otherwise occur. As set forth throughout the present application and documents cited therein, the IRM compounds are well known to be useful for a very wide range of diseases and treatments on various tissues, including mucosal surfaces, but it has been found that side effects such as irritation can also occur from prolonged contact and are particularly challenging on mucosal surfaces where the tissue is more sensitive.

There is no reason one skilled in the art would doubt that general usefulness and applicability of IRM compounds for treating diseases generally on mucosal surfaces. Nor would one skilled in the art doubt the benefits of being able to proactively remove the IRM from contact with a mucosal surface to reduce side effects or that this discovery would be generally applicable and useful. Moreover, with knowledge of the present application in mind, it would not require any undue experimentation to practice the claimed invention. To the contrary, such testing would be clear and straightforward in view of the present application disclosure.

Accordingly, Applicants believe that the claimed invention is properly enabled and therefore request that the rejection under 35 U.S.C. 112, first paragraph, be withdrawn.

In view of the above, it is submitted that the application is in condition for allowance. Reconsideration and favorable action are therefore requested.

Respectfully submitted,

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